K070858
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APR 16 2007

510(k) Special Summary
Medgraphics Express Series

Date of Summary	March 27, 2007
Company Name	Medical Graphics Corporation 350 Oak Grove Parkway St. Paul, MN 55127
Contact Name	Mary E. Donlin
Classification name:	73BZLOxygen Uptake Computer
Product Name:	Express Series
CFR section:	868.1730 Oxygen Uptake Computer
Device Class:	Class IIa

Predicate Device: Medgraphics Ultima System K061731 manufactured by Medical Graphics Corporation, 350 Oak Grove Parkway, St. Paul, MN 55127.

Description: The Express Series is a cardiopulmonary exercise or resting metabolic measurement system with an integrated touch screen computer that provides breath by breath measurements of flow, oxygen uptake and carbon dioxide production.

Intended Use: Medgraphics Express Series is intended for medical applications requiring a non-invasive assessment of the cardiopulmonary response to exercise or measurement of energy expenditure using indirect calorimetry.

Comparison: Direct comparison with the predicate device was made with acceptable conclusions.

Discussion: Laboratory and clinical testing of 10 systems has shown the Express Series to have substantial equivalence in performance and precision to the predicate device. Tandem gas exchange system validator studies performed with the predicate device produced comparative data output with less than 5% variability for VO_2, VCO_2 and tidal volume.

Conclusion: The Medgraphics Express Series is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 2007

MedGraphics
c/o Mary E. Donlin
350 Oak Grove Parkaway
St. Paul, MN 55127

Re: K070858
Trade/Device Name: Cardio-Pulmonary Exercise Stress System
Regulation Number: 21 CFR 868.1730
Regulation Name: Oxygen uptake computer
Regulatory Class: Class II
Product Code: BZL
Dated: March 21, 2007
Received: March 28, 2007

Dear Ms. Donlin:

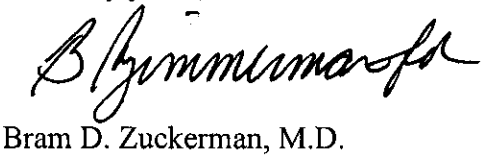
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070858

Indications for Use

510(k) Number (if known): K

Device Name: Medgraphics Express Series

Indications for Use:

The Express Series uses the direct measurement of oxygen uptake to objectively and non-invasively assess cardiac and pulmonary function during exercise. The system can be used to screen for early signs of cardiac and pulmonary dysfunction; differentiate heart and lung disease; assess dyspnea complaints; classify patients according to severity of disease as a guide for patient management; establish an optimal exercise prescription and training program; evaluate the efficiency of prescribed therapy.

The Express Series uses the direct measurement of oxygen uptake and carbon dioxide production to provide nutritional assessment, to optimize nutritional supplements and quantify substrate utilization.

The Express Series can also provide direct Fick determination of cardiac output using real time oxygen uptake measurements.

Prescription Use __X___ AND/OR Over the Counter use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE TO USE ANOTHER PAGE IF NEEDED)

B Kumimoto

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070858